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Participant Information Sheet

Women with a medical diagnosis of Hyperemesis Gravidarum

Project Title: Women's Experience Survey of Hyperemesis Gravidarum: Life impacts, experiences of treatment and perceptions of Chinese herbal medicine

Project Summary: This study comprises an online questionnaire survey designed to understand the experiences of Australian-based women of HG health-related treatments and levels of satisfaction of treatment received; the impact of HG on women's lives and participation in daily activities; and finally, unmet treatment needs and perceptions of Chinese herbal medicines. The survey is conducted exclusively online. The survey will take approximately 10-15 minutes to complete. Women 18 years and older and who are presently or who have been diagnosed with HG in the previous 24 months are invited to participate.

Introduction

You are invited to participate in a project called 'Women's Experience Survey of Hyperemesis Gravidarum: Life impacts, experiences of treatment and perceptions of Chinese herbal medicine.' You are being invited because you are currently experiencing or have previously experienced pregnancy-related nausea and vomiting and were diagnosed with Hyperemesis gravidarum (HG). Hyperemesis gravidarum (HG) is complication of pregnancy that some women experience. It is characterised as a severe form of pregnancy-related nausea and vomiting that can persist after the first trimester and can potentially cause complications if left untreated.

This Participant Information Sheet (PIS) provides more information about this survey and explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. Before deciding whether to participate, you might want to talk about it with a relative, friend or healthcare professional. Participation in this survey is voluntary and anonymous. If you don't wish to take part, you don't have to, and deciding not to take part will not affect any healthcare related treatments you are seeking.

By checking eligibility and completing the survey, you indicate your consent for the collection and use of information provided for this research project.

What is the purpose of this research?

This study comprises an online survey exploring the experiences of women diagnosed with Hyperemesis Gravidarum. The survey is part of a broader review project investigating the evidence for Chinese herbal medicines for treating symptoms including pregnancy-related nausea and vomiting associated with HG. This project aims to increase knowledge of the treatment and management of pregnancy-related nausea and vomiting, and associated symptoms experienced by women diagnosed with HG.

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ABN 53 014 069 881 CRICOS Provider No: 00917K
Locked Bag 1797 Penrith NSW 2751 Australia
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Specifically, this study is designed to understand the experiences of Australian-based women of HG health-related treatments and levels of satisfaction of treatment received; the impact of HG on women's lives and participation in daily activities; and finally, unmet treatment needs and perceptions of Chinese herbal medicines. Your participation will help with better understanding HG impacts from the perspective of women affected. The research outcomes will also inform clinical decision making and support patient advocacy.

How is the study being paid for?

There is no external funding for this project. The project is an internal project sponsored by the Chinese Medicine Centre at the School of Health Sciences at the Western Sydney University.

What will I be asked to do?

After reading this Participant Information Sheet (PIS) and if you decide to take part in this research project, you will be invited to scan the QR code or select the web-link that takes you to the survey. Here, you will be invited to read the survey introduction and the consent form (Participant Consent Form) and indicate that you:

- Understand what you have read in the Participant Information Sheet and the Participant Consent Form; and
- Consent to progress to the survey eligibility questions. If eligible, to continue to the main survey, and with survey completion, consent for your survey response information to be included as part of the study's data analyses, reporting and potential reuse in future HG-related studies.

This online screening process commences with a completion consenting process. The online screening process comprising three (3) questions asking about your age, the time length of the most recent HG diagnosis and who made the diagnosis. The screening aims to identify potential participants who meet the eligibility criteria. If you are ineligible, your participation in the survey will end and you will be thanked for your time.

If eligible, you will be asked to complete a series of 42 questions divided into 5 sections. These are:

- Section 1: Diagnosis of HG (8 questions, including pregnancy frequency, HG diagnosis frequency, onset, symptom nature, duration, and severity.)
- Section 2: Participant demographics (8 questions, including weight, height, family HG diagnosis history, smoking or vaping usage, postal code and cultural background.)
- Section 3: Impact of HG on women's lives (9 questions, including work status, days off due to HG and life impacts, for example, sleep quantity, impact on social activities and change of moods or feelings.)
- Section 4: The HG treatment experience (11 questions, including strategies of symptom self-

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management, prescribed medications, treatments and satisfaction; side-effects and additional care needs.)

- Section 5: Perceptions of Chinese herbal medicine (6 questions, including confidence in understanding CHM, and factors influencing usage of CHM.)

The survey concludes after section 5, and you will be thanked for your time.

How much of my time will I need to give?

The survey can take approximately 10-15 minutes to complete from start to end. Please note that completing the survey may necessitate additional time due to individual differences in reflecting on and recalling information.

What benefits will I, and/or the broader community, receive for participating?

You may not benefit directly from participating in this research. This is because the research outcomes are for future happenings. However, your active involvement in this study will positively impact women who may encounter HG in the future, as the research outputs aim to inform research, clinical decision-making, and patient advocacy.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

Yes, it may involve both physical and psychological discomfort and inconvenience on your time.

Completing the study forms and outcome measures may pose some risks. While many of the questions are general, you are being asked to reflect upon your HG experiences (including intractable nausea and vomiting in pregnancy) because of a current or previous HG diagnosis. This might cause feelings of discomfort or distress, especially if you are tired or fatigued. If you are currently experiencing nausea and vomiting, you will also be asked to complete the PUQE-24 which is asking you to reflect on your current feelings of nausea and vomiting. You are advised to consider your present health status on whether to participate.

Completing the survey may also impact on your time, causing inconvenience. However, the survey has been tested and designed to be approximately 10-15 minutes in length to reduce the time burden and inconvenience. The survey includes multiple-choice questions to decrease the time burden that open-ended questions might otherwise cause. The survey has been carefully reviewed by expert group of medical and health care practitioners, and consumer advocates to balance the aims of the research with the duration.

It is important to emphasise that ensuring your safety and well-being is our main priority. However, the unpredictable nature of HG symptoms means if you are currently experiencing nausea and vomiting it may pose challenges to effectively complete the survey in a single sitting. Therefore, please avoid those situations in which you usually feel sick, such as in the morning, after eating, and/or if feeling tired or exhausted. If you experience mild discomfort during the survey, you may consider one of the following options:

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1) Stop answering the survey questions and rest before resuming.
2) Relax and rest until you feel better.
3) Withdraw from the study if you prefer.
4) Stop completing the survey and hit submit.

If you have feelings of discomfort of distress thinking about your experiences, please contact your GP, or the following help lines:

- **Beyond Blue** provide access to information, advice and support mental health. Telephone 1300 224 636
- **PANDA** (Perinatal Anxiety & Depression Australia) supports the mental health of parents and families during pregnancy and in their first year of parenthood. Telephone 1300 726 306
- **Lifeline** provides access to 24-hour support if you are experiencing emotional distress Telephone 13 11 14

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in various forums, including journal publications, conference posters, seminars, and presentations, which are likely to be obstetric (medical), pregnancy-based or Chinese medicine-related academic forums. The results may also contribute to a future HDR research thesis.

Importantly, in any publication and/or presentation, information will be aggregated, meaning that all survey responses are grouped, meaning it will not be possible to identify individual participant survey responses. Due to the anonymous nature of our survey, the likelihood of you being identified is negligible.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the raw data you provide and that your data will contribute only to HG projects. Please note that the minimum retention period for data collection is five years post-publication.

The data in this project will be retained for five years or more before it is securely disposed of. This is because the researchers are also asking that you agree to allow the data to potentially be used in future HG-related or Chinese Medicine (CM)-related projects. (This is described on page 6.)

Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate, you can withdraw at any time without giving a reason by not submitting the survey.

Please note once the survey has been submitted it may not be possible to withdraw your data from the study if you change your mind, as the data is not linked to identifying information.

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Whatever your decision to take part or not take part, it will not affect your routine care, your relationship with professional staff, organisations or your care facility, or your relationship with Western Sydney University or the researchers.

What if I require further information?

Please email womenshgsurvey@westernsydney.edu.au or contact one of the research team members listed below should you wish to discuss the research further before deciding whether to participate.

Jianping Luo, Chief Student researcher.

- Email: womenshgsurvey@westernsydney.edu.au

Dr Sean Walsh, Coordinating Principal Investigator/supervisor:

- Email: Sean.Walsh@westernsydney.edu.au

Professor Xiaoshu Zhu, Principal Investigator and Co-supervisor

- Email: x.zhu@westernsydney.edu.au

Privacy Notice

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.

The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses, and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Services: humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, please keep a copy of the Participant Consent Form. The information sheet is for you to keep. Consent to participate is completing and submitting the survey online.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H15773.

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Explanation of Consent

What will happen to my information if I agree to it being used in other projects?

Thank you for considering being a participant in a university research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to extended consent.

What does this mean?

When you agree to extended consent, it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

The researchers will allow this data to be used by HG or CM related studies.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use will not have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

The researchers want to keep the data for *5 of more* years for possible re-use. After this time the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

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